# ENTERNAL FORMULATION DESIGNED FOR OPTIMIZED NUTRIENT ABSORPTION AND WOUND HEALING

This application is a continuation-in-part of U.S. application Ser. No. 08/172,857 entitled: "ENTERAL FORMULATION DESIGNED FOR OPTIMIZED NUTRIENT ABSORPTION AND WOUND HEALING" filed Dec. 23, 1993, now abandoned.

## BACKGROUND OF THE INVENTION

The present invention relates to nutritionally fortified pharmaceutical compositions. More specifically, the present invention relates to compositions for use in intensive care patients.

Intensive care patients describe a broad population of patients who may suffer from a variety of diseases or insults. These patients, however, exhibit some similar requirements. For example, patients suffering from traumatic injury, burns, post-surgery, and some disease states have a significant need for increased nutrients and energy as compared to individuals who are not challenged by such metabolic stress. Indeed, non-essential nutrients and substances that a body typically can synthesize in adequate supply may become limiting. Additionally, absorption of nutrients from the gut can be compromised even when no direct injury to the gastrointestinal system exists.

Many intensive care patients are fed either with parenteral formulations or enteral formulations either to replace or supplement a typical diet. For example, in 1991, of an estimated 2.4 million trauma patients in the United States, 13% (310,000) required nutrition support beyond food. Of these patients, 62% of the patients were supported using enteral nutrition, tube-feeding and 30% oral supplements, while 38% were initially supported using parenteral nutrition and progressed to tube-feeding, if they survived. Similarly, of about 106,000 burn patient admissions in 1991 in the U.S., approximately 20% (21,000) required nutritional support. Of this group, 95% were started on enteral nutrition, 70% began on tube feeding and 30% started on oral supplements.

Numerous enteral formulations have been targeted for trauma and burn patients. These products include: Mead-Johnson's TRAUMACAL®; Sandoz's IMPACT®; Abbott Laboratories' ALITRAQ®; and McGaw's IMMUN-AID®. Although such products are used in an attempt to treat and/or provide nutritional requirements for such patients, the inventors of the present invention do not believe that these products meet the needs of such patients.

Accordingly, a need exists for an enteral nutritional formulation which meets the nutrient requirements of intensive care patients who may have altered nutritional requirements and compromised absorptive capacity.

## SUMMARY OF THE INVENTION

The present invention provides an enteral nutritional formulation that meets the nutrient requirements of intensive care patients who may have compromised absorption capacity. The present invention meets the unique nutrient needs of the patient that are generated due to tissue repair and healing requirements.

To this end, in an embodiment, the present invention provides a method for providing nutritional support to intensive care patients comprising the step of administering a therapeutically effective amount of a composition. The composition preferably includes a protein source; a carbohydrate source; and a lipid source. The protein source is produced with the use of pancreatic enzymes, resulting in a unique peptide profile.



In an embodiment, a method for providing nutritional support to an intensive care patient is provided comprising administering a therapeutically effective amount of a composition with an improved protein source. The protein source contains a protein hydrolysate and free amino acids; the protein hydrolysate includes less than approximately 35%, by weight, peptides having a chain length of more than five amino acids.

In another embodiment, a method for providing nutritional support to a patient is provided that utilizes a composition containing approximately 80% to 85% of protein hydrolysate and approximately 15% to 20% of free amino acids. Preferably, the caloric density of the composition is at least 1.3 Kcal/ml.

In an embodiment, the protein hydrolysate includes less than approximately 35% by weight peptides having a chain length of more than five amino acids.

In yet another embodiment, the free amino acids of the composition comprise less than approximately 20% by weight of the protein source.

In an embodiment, the protein source comprises less than approximately 20% by weight peptides having a chain length of more than nine amino acids.

In another embodiment, the cysteine content of the protein source is at least approximately 0.25% of the total calories.

In an embodiment, a method for providing nutritional support to an intensive care patient is provided comprising administering a therapeutically effective amount of yet another composition. The composition comprises a protein source containing less than 20% peptides, by weight, having a chain length of more than nine amino acids.

If desired the composition can include sources of: arginine; proline; and/or cysteine. Sufficient cysteine is included to replenish the intracellular glutathione of the treated patient. Preferably, the composition contains at least 0.25% of its total calories from cysteine.

An advantage of the present invention is that it provides an enteral nutritional formulation that is designed to optimize nutrient absorption and wound healing in trauma patients.

Moreover, an advantage of the present invention is to provide a composition having a high protein content, a high lipid content, and a high caloric density to meet protein and energy needs.

Furthermore, an advantage of the present invention is to provide a composition that has reduced water and carbohydrate content, reducing the risk of diarrhea due to carbohydrate intolerance, hyperglycemia, over hydration, and the like.

Still further, an advantage of the present invention is that nutrient malabsorption is reduced by the absence of whole proteins and by the use of protein hydrolysate, free amino acids and medium chain triglycerides in the enteral formulation of the present invention.

Additionally, an advantage of the present invention is that it is a ready-to-use formulation, and not a powder that requires mixing before use, reducing the risk of bacterial contamination during the mixing process.

Moreover, pursuant to the present invention, the use of certain components promotes healing and tissue repair/cell division.